

REMARKS

Applicants wish to thank Examiner Bland for the attention accorded to the instant application, and respectfully requests reconsideration of the application as amended.

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, 37, 38 and 40-54 are pending. Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, 37, 38 and 40-51 have been examined on the merits. Previously submitted Claims 52-54 have been withdrawn in the Official Action. Applicants reserve the right to re-file the subject matter of Claims 52-54 in a continuing application.

Claim 20 has been cancelled. Claim 1 has been amended to recite the subject matter of previously filed Claim 37. Claim 37 has been cancelled. Claims 16 and 41 have been amended to reflect proper dependencies. Claim 45 has been amended to remove the term “and suffering from a disease or disorder caused by accumulation of lactic acid in the colon.” Claims 1 and 38 have been amended to remove the term “aged mammal.”

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, 37 and 42-46 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 1, 5-13, 16-20, 27, 28, 30, 32-35, 38 and 42 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Livesey et al. (European Journal of Clinical Nutrition (1993) 47, 419-430) (Livesey).

Claims 1, 5-13, 16-20, 24, 27-28, 30, 32-35, 27, 28, 40-44 and 47-51 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Canadian Patent Application 2,340,103 to Stahl et al. (Stahl) in view of Am. J. Clin. Nutr 2000, 72: 1503-9 (Jie), International Patent WO 02/39832 to Brokx et al (Brokx), Livesey, and “Medical Nutrition Therapy for Lower

Gastrointestinal Tract Disorders,” Krause’s Food, Nutrition and Diet Therapy (ed. 10), 2000, pages 667-694 by Beyer (Beyer).

Claims 1, 5-13, 16-20, 24, 27-28, 30, 32-35, 37, 38 and 40-51 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and U.S. Patent 5,443,826 to Borody (Borody).

Claims 26 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Livesey in view of U.S. Patent 5,601,863 to Borden et al. (Borden). Claims 26 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Beyer and further in view of Borden. Claims 26 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody and further in view of Borden.

In view of the following remarks, Applicants request further examination and reconsideration of the present patent application.

Rejections under 35 U.S.C. § 112

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, 37 and 42-46 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 20 has been cancelled. Claim 1 has been amended to include the groups listed in previously filed Claim 37. Claim 37 has been cancelled. Claims 16 and 41 have been amended to reflect proper dependencies. Also, Claim 45 has been amended to remove the term “suffering from a disease or disorder caused by accumulation of lactic acid in the colon.”

Thus, Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35 and 42-46 distinctly claim the subject matter which Applicants regard as the invention. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35 and 42-46 is earnestly solicited.

Rejections under 35 U.S.C. §102

Claims 1, 5-13, 16-20, 27, 28, 30, 32-35, 38 and 42 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Livesey.

Livesey discloses administration of a confection containing polydextrose and lactitol to a range of people of different ages. See page 420 of Livesey. Livesey discloses this administration in an effort to study the hydrogen production of from different alternative carbohydrate is similar or not. See Abstract of Livesey.

The Official Action states that Livesey's administration to people of ages 32, 39 and 46 discloses administration to aged mammals. Claims 1 and 38 have been amended to remove the term "aged mammal." Livesey does not disclose the treating of any group other than individuals of varying ages.

Thus, the rejection of Claims 1, 5-13, 16-20, 27, 28, 30, 32-35, 38 and 42 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-19, 27, 28, 30, 32-35, 38 and 42 is earnestly solicited.

Rejections under 35 U.S.C. §103

Claims 1, 5-13, 16-20, 24, 27-28, 30, 32-35, 27, 28, 40-44 and 47-51 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey, and Beyer.

The combination of Stahl, Jie, Brokx, Livesey and Beyer does not teach or suggest the claimed invention.

The deficiencies of Livesey are discussed above. None of the Stahl, Jie, Brokx or Beyer references, alone or in combination, cure these deficiencies.

Newly cited reference Stahl discloses the incorporation of a mixture of two different carbohydrates in dietetic nutritions and pharmaceuticals to stimulate health-promoting

microorganisms present in the natural flora of the large intestine. See page 3 lines 15-21 of Stahl. Stahl further discloses that in a preferred embodiment, a mixture of different carbohydrates will promote lactic acid bacteria to a surprising degree in the intestine. See page 7 line 27 to page 8 line 5 of Stahl. Stahl does not teach or suggest the use of polydextrose and lactitol.

Stahl discloses the use of a mixture of carbohydrates, which remain undigested in the gastrointestinal tract. The mixture contains at least carbohydrate compounds A and B, wherein A is a monosaccharide and B is a polysaccharide. The Official Action correctly states that Stahl does not disclose polydextrose and lactitol, but teaches an implausible position, that it would be obvious to select them as the two carbohydrates of Stahl.

Stahl does not disclose, teach or suggest the use of lactitol, because, at the least, lactitol is not a carbohydrate. The chemical group called "carbohydrates" comprises only organic compounds with the general formula $C_m(H_2O)_n$. Carbohydrates consist only of carbon, hydrogen and oxygen. Hydrogen and oxygen are always present in a ration of 2:1, as further discussed in Exhibit A enclosed herewith. Polydextrose, as disclosed by Stahl, is based on a polysaccharide backbone, but it contains minor amounts of other components deriving from its production.

Lactitol, as recited in independent Claims 1, 38, 47 and 48 of the present application, is not a carbohydrate. Lactitol is a polyalcohol or polyol with a molecular formula of $C_{12}H_{24}O_{11}$, as further discussed in Exhibit B enclosed herewith. Lactitol does not have a ratio of hydrogen to oxygen of 2:1.

Stahl does not disclose, teach or suggest selecting polydextrose as the polysaccharide component B, therefore it can not be considered obvious to select polydextrose, as recited in independent Claims 1, 38, 47 and 48 of the present application. There is a vast number of carbohydrates, not all of them promote lactic acid bacteria. Few of the number of carbohydrates

which do promote lactic acid bacteria will act like polydextrose to prevent accumulation of lactic acid in the colon.

Polydextrose promotes lactic acid bacteria and prevents accumulation of the so produced lactic acid. Other carbohydrates, like inulin, also promote lactic acid bacteria but do not have the capacity to prevent accumulation of the produced lactic acid. See page 2 lines 23-26 and Examples 1 and 2 of the present application.

The promotion of lactic acid bacteria is not synonymous with increasing lactic acid in the colon. Lactic acid is produced by the lactic acid bacteria, but other bacteria will quickly consume the so produced lactic acid. Polydextrose and polyol provide the energy for proliferation of the lactic acid bacteria in the colon by being slowly fermented throughout the colon. Polydextrose does not prevent the production of lactic acid. Polydextrose promotes lactic acid bacteria, and, thus, also promotes the production of lactic acid. However, polydextrose prevents accumulation of the lactic acid, because polydextrose maintains a continued beneficial bacterial fermentation in the colon so that all lactic acid produced is also consumed.

Assuming, *pro arguendo*, a person of ordinary skill in the art would have selected polydextrose as the polysaccharide component B of Stahl, they would not then select lactitol as the monosaccharide component A since lactitol is not a monosaccharide. Lactitol is not even a carbohydrate. Therefore, Stahl does not disclose, teach or suggest an administration of polydextrose along with a polyol, as recited in independent Claims 1, 38, 47 and 48, and all claims depending therefrom.

Thus, without the Stahl reference, the rejection under 35 U.S.C. §103(a) cannot stand. Withdrawal of the rejection based on the foregoing remarks alone is respectfully requested.

Jie discloses a drop in pH levels as polydextrose intake increases, which would aggravate a condition where a low pH level caused by lactic acid accumulation is causing an imbalance in

colon fermentation. See page 1507, Table 4 of Jie. Further, Jie discloses the use of polydextrose alone in water. Jie does not disclose an administration of polydextrose along with a polyol, as recited in independent Claims 1, 38, 47 and 48, and all claims depending therefrom.

Newly cited reference Brokx discloses the administration of lactitol contained in a food product to increase the amount of bifidobacteria in the gut of a person. See page 2 lines 7-21 of Brokx. Brokx does not disclose, teach or suggest the administration of both lactitol, a polyol, and a polydextrose to increase the amount of bifidobacteria or reduce lactic acid accumulation in the colon, as recited in independent Claims 1, 38, 47 and all claims depending therefrom.

The deficiencies of Livesey have been discussed above. Livesey has further deficiencies regarding the present rejection. Livesey discloses that when humans consume polydextrose and lactitol, the hydrogen breath test shows an increase in hydrogen in excess of what is expected. The hydrogen breath test disclosed by Livesey is a test generally used to measure lactose intolerance. The test subjects are given lactose and the hydrogen is measured to indicate whether the lactose has been digested and absorbed before it reaches the colon, as it does in healthy subjects, or whether the lactose reaches the colon and produces hydrogen upon fermentation, indicating lactose intolerance.

In the Livesey disclosure, the increased hydrogen production of polydextrose and lactitol shows that some unspecified carbohydrate is fermented in the colon and that the fermentation rate is increased, thus emitting more hydrogen. However, there is no way of knowing what is actually occurring in the colon and whether there is accumulation of lactic acid because of the increased fermentation rate. The excess hydrogen of Livesey could come from harmful bacterial fermentation as easily as it could come from beneficial fermentation. The hydrogen production does not tell whether lactic acid is produced and/or consumed. There is no indication in Livesey that accumulation of lactic acid can be prevented and that certain disorders can be treated with

the combination of polydextrose and lactitol as recited in Claims 1, 38, 47 and 48, and all claims depending therefrom of the present application.

Livesey only discloses administration to an aged human population and not the groups recited in Claims 1, 38, 47 and 48, and all claims depending therefrom.

Newly cited reference Beyer discloses that prebiotics or fermentable sugars may be used to treat various diseases including diarrhea, lactose intolerance, inflammatory bowel disease and pouchitis. The page numbers cited by the Examiner differ from the article provided by the Examiner, attached to the present rejection. Even though the Examiner may have erred in providing the correct page numbers, the article provided discloses the role of fiber in nutrient absorption, which does not disclose the subject matter of the claimed invention. Further, assuming that another portion of Beyer does state that fermentable sugars can be used to treat diarrhea and other diseases, neither lactitol nor polydextrose are fermentable sugars. Lactitol is not a sugar at all and polydextrose is not fermentable, and is considered by those skilled in the art to be generally non-fermentable.

The portions of Beyer provided describe a huge number of different ways in which disorders in the gastrointestinal tract can be treated. The combination of polydextrose with lactitol is not disclosed. Further, Beyer states that “Sugar alcohols, lactose, fructose and large amounts of sucrose may worsen osmotic diarrheas and may have to be limited.” See page 671, right hand column, third full paragraph of Beyer. This disclosure would motivate a person of ordinary skill in the art to look away from the Beyer disclosure.

Further, Beyer offers more disclosures that teach against the present invention, including that to treat inflammatory bowel diseases, “a diet that limits whole fibrous foods might be used...” See page 681-686 of Beyer. Polydextrose is a fibrous food, Beyer discloses that it should be limited. Beyer also suggests that “the use of fermentable fibers” is among the

therapeutic strategies being considered. See page 685, left hand column of Beyer. Polydextrose is a substantially non-fermentable fiber. Thus, Beyer does not suggest or teach polydextrose for inflammation. Beyer mentions pouchitis in the right hand column of page 692 but suggests that antibiotics are the primary form of therapy.

Further, even if Beyer did disclose the use of prebiotics to treat diseases including diarrhea, lactose intolerance, inflammatory bowel disease and pouchitis, which it does not, there is no disclosure of the administration of polydextrose to reduce lactic acid accumulation, as recited in Claims 1, 38, 47 and 48, and all claims depending therefrom.

Based on the deficiencies of the above references, there is no teaching, suggestion or motivation for one of ordinary skill in the art to practice or use the claimed method of reducing lactic acid accumulation in the colon of a subject from the groups recited in Claims 1, 38, 47 and 48, and all claims depending therefrom. Thus, the rejection of Claims 1, 5-13, 16-20, 24, 27-28, 30, 32-35, 27, 28, 40-44 and 47-51 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-19, 24, 27-28, 30, 32-35, 27, 28, 40-44 and 47-51 is earnestly solicited.

Claims 1, 5-13, 16-20, 24, 27-28, 30, 32-35, 37, 38 and 40-51 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody.

The deficiencies of Stahl, Jie, Brokx and Livesey are discussed above. Borody does not cure those deficiencies.

Newly cited reference Borody discloses the treatment of various diseases related to the presence of abnormal microflora in the gastrointestinal tract. See column 1 lines 65-69 of Borody. Borody further discloses the removal of a person's enteric microflora and the substitution of the removed microflora with an amount of fresh or dried feces from another human donor. See column 3 lines 57-68 and Claim 1 of Borody. Removing bacteria by lavage

and restoring the microflora by eating live bacteria is a totally different disclosure from eating a combination which does not contain microbes. Polydextrose and polyol are both chemicals free from live bacteria. Thus Borody does not give any suggestion or motivation to a person of ordinary skill in the art to practice the method of the claimed invention.

At the least, Borody does not disclose a method for treating a subject through administration of polydextrose and lactitol to reduce lactic acid accumulation in the colon, as recited in Claims 1, 38, 45, 47, 48 and all claims depending therefrom. Therefore, the combination of Stahl in view of Jie, Brokx, Livesey and Borody would not disclose, teach or suggest this feature.

Thus, the rejection of Claims 1, 5-13, 16-20, 24, 27-28, 30, 32-35, 37, 38 and 40-51 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-19, 24, 27-28, 30, 32-35, 38 and 40-51 is earnestly solicited.

Claims 26 and 28 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Livesey in view of Borden.

The deficiencies of Livesey are fully discussed above. Livesey does not disclose a method for treating a subject selected from the group consisting of a young mammal at the age of weaning, a young mammal suffering from milk crust, a mammal treated with antibiotics, a mammal suffering from a food allergy, a mammal with a short intestine, or a subject with acidosis, osteoporosis or diarrhea through administration of at least one polyol and polydextrose to reduce lactic acid accumulation in the colon, as recited in Claim 1, from which Claims 26 and 28 depend. Borden does not cure these deficiencies.

Borden teaches polymerization of polydextrose by exposing the polydextrose to hydrogen gas in the presence of a hydrogenation catalyst or a hydride donor. See column 1 line 59 to column 2 line 2. Borden does not teach or suggest a method of treatment for any subject.

Further, Borden does not teach a method to reduce lactic acid accumulation in the colon through administration of polydextrose and lactitol, as recited in Claim 1, from which Claims 26 and 28 depend. Therefore, the combination of Livesey with Borden would not disclose this feature.

Thus, the rejection of Claims 26 and 28 under 35 U.S.C. §103(a) is overcome.
Withdrawal of the rejection and allowance of Claims 26 and 28 is earnestly solicited.

Claims 26 and 28 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Beyer and further in view of Borden.

The deficiencies of Stahl, Jie, Brokx, Livesey and Beyer are discussed above. Specifically, the combination of Stahl, Jie, Brokx, Livesey and Beyer does not disclose a method for treating a subject through administration of at least one polyol and polydextrose to reduce lactic acid accumulation in the colon, as recited in Claim 1, from which Claims 26 and 28 depend. Borden does not cure these deficiencies.

Borden does not teach or suggest a method of treatment for any subject. Further, Borden does not teach a method to reduce lactic acid accumulation in the colon through administration of polydextrose and lactitol, as recited in Claim 1, from which Claims 26 and 28 depend. Therefore, the combination of Stahl in view of Jie, Brokx, Livesey and Beyer and further in view of Borden does not disclose this feature.

Thus, the rejection of Claims 26 and 28 under 35 U.S.C. §103(a) is overcome.
Withdrawal of the rejection and allowance of Claims 26 and 28 is earnestly solicited.

Claims 26 and 28 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody and further in view of Borden.

The deficiencies of Stahl, Jie, Brokx, Livesey and Borody are discussed above. Specifically, the combination of Stahl, Jie, Brokx, Livesey and Borody does not disclose a method for treating a subject through administration of at least one polyol and polydextrose to

reduce lactic acid accumulation in the colon, as recited in Claim 1, from which Claims 26 and 28 depend. Borden does not cure these deficiencies.

Borden does not teach or suggest a method of treatment for any subject. Further, Borden does not teach or suggest a method to reduce lactic acid accumulation in the colon through administration of polydextrose and lactitol, as recited in Claim 1, from which Claims 26 and 28 depend. Therefore, the combination of Stahl in view of Jie, Brokx, Livesey and Borody and further in view of Borden does not disclose this feature.

Thus, the rejection of Claims 26 and 28 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection and allowance of Claims 26 and 28 is earnestly solicited.

Applicant believes that the foregoing remarks and amendments submitted herein provides a complete response to the Office Action, and the present case is in condition for allowance. Therefore, in view of the foregoing, Applicant respectfully requests reconsideration, withdrawal of all rejections, and allowance of all pending claims in due course.

If the Examiner believes that a telephone conference with the Applicants attorneys would be advantageous to the disposition of this case, the Examiner is requested to contact the undersigned, at the number provided below.

Respectfully submitted,

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